

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT: Wands *et al.*

SERIAL NUMBER:

EXAMINER:

FILING DATE:

ART UNIT:

FOR: DIAGNOSIS AND TREATMENT OF MALIGNANT NEOPLASMS

July 11, 2001

Boston, Massachusetts

Assistant Commissioner for Patents  
Washington, D.C. 20231

**PRELIMINARY AMENDMENT**

Prior to examination, please amend the application as follows.

**In the specification:**

On page 1, line 2, after the title, insert:

2025 RELEASE UNDER E.O. 14176

APPLICANTS: Wand et al.

FILED: Herewith

This application is a divisional of patent application U.S. Serial Number 09/436,184, filed on November 8, 1999, the entire contents of which is hereby incorporated by reference.

APPLICANTS: Wand et al.

FILED: Herewith

In the claims:

Cancel claims 10-27 and 29-38.

Amend claim 1, and add new claims 39-54.

APPLICANTS: Wand et al.

FILED: Herewith

1. A method for diagnosing a malignant neoplasm in a mammal, comprising contacting a bodily fluid from said mammal with an antibody or fragment thereof which binds to an human aspartyl (asparaginyl) beta-hydroxylase (HAAH) polypeptide under conditions sufficient to form an antigen-antibody complex and detecting the antigen-antibody complex.
39. The method of claim 1, wherein said antibody is a single chain Fv molecule.
40. The method of claim 1, wherein said antibody is a FB50 single chain Fv molecule.
41. A method of diagnosing a malignant neoplasm in a mammal, comprising contacting a bodily tissue from said mammal with an antibody or fragment thereof which binds to a HAAH polypeptide under conditions sufficient to form an antigen-antibody complex and detecting the antigen-antibody complex.
42. The method of claim 41, wherein said tissue is a biopsy of a solid tumor.
43. The method of claim 1, wherein the antigen-antibody complex is detected by a label selected from consisting of an enzymatic label, a fluorescent label, a chemiluminescent label, a radioactive label, and a dye label.
44. The method of claim 41, wherein the antigen-antibody complex is detected by immunohistochemical staining.
45. The method of claim 1, wherein said neoplasm is a hepatocellular carcinoma.
46. The method of claim 1, wherein said neoplasm is a cholangiocarcinoma.
47. The method of claim 41, wherein said neoplasm is a hepatocellular carcinoma.
48. The method of claim 41, wherein said neoplasm is a cholangiocarcinoma.

APPLICANTS: Wand et al.

FILED: Herewith

49. The method of claim 41, wherein said antibody is a single chain Fv molecule.
50. The method of claim 41, wherein said antibody is a FB50 single chain Fv molecule.
51. The method of claim 1, wherein said neoplasm is a glioblastoma.
52. The method of claim 1, wherein said neoplasm is a neuroblastoma.
53. The method of claim 41, wherein said neoplasm is a glioblastoma.
54. The method of claim 41, wherein said neoplasm is a neuroblastoma.

APPLICANTS: Wand et al.

FILED: Herewith

## **REMARKS**

Claims 1-9, 28, and 39-54 are pending, claims 10-27 and 29-38 having been canceled as being drawn to a non-elected invention. Claim 1 has been amended. New claims 39-54 have been added. The amendment to claim 1, new claims 39-40, and new claims 49-50 are supported by disclosure on page 2, lines 18-25, of the specification. New claims 41-42 are supported by disclosure on page 1, lines 31-32, of the specification. New claims 43-44 are supported by disclosure on page 15, lines 19-20, and on page 24, line 32, to page 25, line 26, of the specification. New claims 45-48 are supported by disclosure on page 22, lines 3-6, of the specification. New claims 51-54 are supported by disclosure on page 17, line 29, and on page 42, lines 30-33, of the specification.

No new matter has been added by this amendment.

## **CONCLUSION**

Applicants believe that the claims are in condition for allowance. The Commissioner is authorized to credit any overpayment or charge any deficiencies to Deposit Account No. 50-0311, Reference No. 21486-032.

Respectfully submitted,



Ingrid A. Beattie, Reg. No. 42,306  
Attorney for Applicants  
c/o MINTZ LEVIN  
One Financial Center  
Boston, Massachusetts 02111  
Tel.: (617) 542 6000  
Fax: (617) 542-2241

APPLICANTS: Wand et al.

FILED: Herewith

Appendix:

In the specification:

On page 1, line 2, after the title, insert:

--This application is a divisional of patent application U.S. Serial Number 09/436,184, filed on November 8, 1999, the entire contents of which is hereby incorporated by reference.--

In The Claims:

Amend claim1 and add new claims 39-54.

1. (Amended) A method for diagnosing a malignant neoplasm in a mammal, comprising contacting a bodily fluid from said mammal with an antibody or fragment thereof which binds to an human aspartyl (asparaginyl) beta-hydroxylase (HAAH) polypeptide under conditions sufficient to form an antigen-antibody complex and detecting the antigen-antibody complex.--

--39. The method of claim 1, wherein said antibody is a single chain Fv molecule.--

--40. The method of claim 1, wherein said antibody is a FB50 single chain Fv molecule.--

--41. A method of diagnosing a malignant neoplasm in a mammal, comprising contacting a bodily tissue from said mammal with an antibody which binds to a HAAH polypeptide under conditions sufficient to form an antigen-antibody complex and detecting the antigen-antibody complex.--

--42. The method of claim 41, wherein said tissue is a biopsy of a solid tumor.--

--43. The method of claim 1, wherein the antigen-antibody complex is detected by

APPLICANTS: Wand et al.

FILED: Herewith

immunohistochemical staining.--

--44. The method of claim 41, wherein the antigen-antibody complex is detected by

immunohistochemical staining.--

--45. The method of claim 1, wherein said neoplasm is a hepatocellular carcinoma.--

--46. The method of claim 1, wherein said neoplasm is a cholangiocarcinoma.--

--47. The method of claim 41, wherein said neoplasm is a hepatocellular carcinoma.--

--48. The method of claim 41, wherein said neoplasm is a cholangiocarcinoma.--

--49. The method of claim 41, wherein said antibody is a single chain Fv molecule.--

--50. The method of claim 41, wherein said antibody is a FB50 single chain Fv

molecule.--

--51. The method of claim 1, wherein said neoplasm is a glioblastoma.--

--52. The method of claim 1, wherein said neoplasm is a neuroblastoma.--

--53. The method of claim 41, wherein said neoplasm is a glioblastoma.--

--54. The method of claim 41, wherein said neoplasm is a neuroblastoma--

TRA 1540145v1